

# **TECHNICAL REPORT**

IVD Test Assay Evaluation of Eagle Bio  
SARS-CoV-2 Antigen IVD Kit Lollipop  
(Self Testing)

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Material Tested:

Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing)

Manufactured by:



Distributed by:

**MULTIPLEX ENTERPRISE**

# TECHNICAL REPORT



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## REPORT TS4-0603-R

Evaluation of COVID-19 In Vitro Diagnostics Medical Devices

Evaluation Letter (3) MDA.600.1/6/29 Jld 6

## Product Details

Product:	Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing)
Product code:	HN06
Lot number:	20210902-01
Manufacturer:	Shenzhen Reagent Technology Co. Ltd.
Requested by:	Multiplex Enterprise
Address:	No. 53a, Jalan Mohd Tahir 8, Klang, 41200 Selangor
Contact number:	+6010 228-0620
Email:	vincentcy20@gmail.com
Date of request:	11 <sup>th</sup> November 2021
Type of sample tested:	Saliva
Intended use:	Self-test

## Executive Summary

The evaluation study was performed to determine the performance of the self-test kit - the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing) in detecting SARS-CoV-2 antigen from human saliva samples. The testing was performed on 30 SARS-CoV-2 positive samples and 30 SARS-CoV-2 negative saliva samples. The comparator assay used was real-time RT-PCR. The positive samples used consisted of samples with Ct values 12.82-29.74. Results showed that the tested device was able to detect SARS-CoV-2 antigen in 29 out of 30 tested positive samples and no detection was made in the negative specimens. As such, the present evaluation showed that the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing) was able to detect SARS-CoV-2 antigen in the tested saliva samples with 96.7% sensitivity and 100% specificity.

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## 1. Purpose and scope

The present evaluation was performed to determine the performance of the self-test kit, the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing) in detecting SARS-CoV-2 antigen from saliva samples. The evaluation is a partial requirement for the product recommendation of use by the Medical Device Authority (MDA).

## 2. Materials and methods

### 2.1 Description of device and intended use

The Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing) is an in vitro diagnostic test for rapid, qualitative detection of SARS-CoV-2 antigen in human saliva samples.

The test is an immunochromatographic membrane assay that utilizes highly sensitive monoclonal antibodies to SARS-CoV-2. The test device is composed of the sample pad, reagent pad, and reaction membrane. The reagent pad contains colloidal gold-conjugated antibodies to SARS-CoV-2 antigen and the reaction membrane contains secondary antibodies to the same antigen and polyclonal antibodies against mouse globulin that are pre-coated on the membrane at the T and C line, respectively. When sample is introduced to the test device, conjugated antibodies at the reagent pad are dissolved and migrate together with the sample along the test strip. If the virus antigen is present in the sample, a complex forms between the conjugated SARS-CoV-2 antibodies and SARS-CoV-2 antigen. The complex is captured by SARS-CoV-2 specific monoclonal antibodies coated at the T line creating a visible line. Absence of the line at the T region suggests a negative result. As a procedural control, a line will always appear at the C region to indicate that sample has been added and membrane wicking has occurred.

### 2.2 Panel of samples

The samples used were archived saliva samples previously obtained from COVID-19 patients. These samples were aliquoted and stored in -80 °C to ensure their integrity. They displayed a Ct value of 12.82–29.74 using real-time RT-PCR. A total of 30 SARS-CoV-2 positive and 30 SARS-CoV-2 negative samples were used for the present evaluation.

### 2.3 Detection of SARS-CoV-2 Antigen using the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing)

Materials included in the kit are the test device, a biohazard bag, and an instruction for use. The test procedure was performed as follows:

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- The test device was removed from its packaging pouch and placed into a tube containing about 1-2 ml of saliva with the collection pad downwards.
- The device was left in the saliva sample for about 1 min before it was removed and placed on a level surface to enable sample migration along the device for about 10-15 min.
- Results were then read. The appearance of two lines at the T and C region indicated the presence of SARS-CoV-2 antigen in the tested sample and a negative result was indicated by the appearance of only one line at the C region.

All procedure was performed in a biosafety cabinet to minimize potential exposure to SARS-CoV-2.

### 3. Results

A total of 30 SARS-CoV-2 positive and 30 negative saliva samples were tested using the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing). Performance of the product was calculated using the Evidence-based Medicine (EBM) Diagnostic Test Calculator (<https://ebm-tools.knowledgetranslation.net/calculator/diagnostic/>; Table 2). Results showed that the tested device was able to detect SARS-CoV-2 antigen in 29 out of 30 tested positive samples, indicating the device's sensitivity of 96.7% (Table 1 & 2). There were no false positives detected when the device was tested on the negative sample panel, indicating the product specificity of 100%.

Concordance analysis showed that there was an almost perfect agreement ( $\kappa=0.967$ ;  $p<0.001$ ) between the test product and the real-time RT-PCR used as the comparator assay.

#### Limitation of the evaluation

Due to constraint of time and resources, the device was not brought out for field testing. Only archived samples were used for the evaluation. To ensure samples' integrity, the samples were stored in -80 °C and were aliquoted to minimize their freeze-thaw cycles.

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Table 1. Detection of SARS-CoV-2 antigen in saliva samples using the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing).

		Real-time RT-PCR (Saliva samples)		Total
		Pos	Neg	
Tested Product	Pos	29	0	29
	Neg	1	30	31
Total		30	30	60

Table 2. Analysis of SARS-CoV-2 antigen detection using the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing) on saliva samples.

Pos	Neg	Sensitivity (95% CI) <sup>a</sup>	Specificity (95% CI)	PPV <sup>b</sup> (95% CI)	NPV <sup>c</sup> (95% CI)	Concordance (Kappa value, $\kappa$ )
29	31	96.7% (83.3-99.4)	100% (88.6-100)	100% (88.3-100)	96.8% (83.8-99.4)	0.967 (p<0.001)

<sup>a</sup> Confidence Interval; <sup>b</sup> Positive predictive value; <sup>c</sup> Negative predictive value

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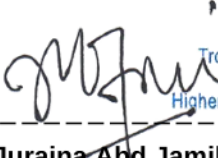

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## 4. Conclusion

Evaluation of the Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing) was successfully completed. The device showed that it was able to detect the presence of SARS-CoV-2 antigen in the tested saliva samples with 96.7% sensitivity and 100% specificity.

### Disclaimer

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